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11 *C. R. Bard, Inc. and*  
12 *Bard Peripheral Vascular, Inc.*

**IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF ARIZONA**

IN RE: Bard IVC Filters Products Liability  
Litigation,

No. 2:15-MD-02641-DGC

**DEFENDANTS' SEPARATE  
STATEMENT OF FACTS IN  
SUPPORT OF MOTION FOR  
SUMMARY JUDGMENT AS TO  
PLAINTIFF CAROL KRUSE'S  
CLAIMS**

CAROL KRUISE, an individual

(Assigned to the Honorable David G.  
Campbell)

23 Plaintiff.

24 || v.

25 C. R. BARD, INC., a New Jersey  
corporation and BARD PERIPHERAL  
26 VASCULAR, INC., an Arizona  
corporation,

## Defendants.

Pursuant to Fed. R. Civ. P. 56(c), Local Rule 56.1(a), and Case Management Order No. 53 (Doc. 5770), Defendants C. R. Bard, Inc. and Bard Peripheral Vascular, Inc. (collectively “Bard”) respectfully submit this Separate Statement of Facts in Support of Motion for Summary Judgment as to Plaintiff Carol Kruse’s Claims.

1. Plaintiff Carol Kruse received a Bard G2® Filter on July 8, 2009. (Ex. A, Fourth Supplemental Plaintiff Fact Sheet of Plaintiff Carol Kruse (hereinafter “PFS”), at § II.2(a).)

2. The Filter is not sold directly to patients. (Ex. B, G2 Filter Instructions for Use (the “G2 IFU”) at page 1.)

3. Plaintiff received her Filter because [REDACTED]

[REDACTED] (Ex. C, Selected Plaintiff Medical Records.)

4. According to Plaintiff’s implanting physician, Dr. Shanon Smith, Plaintiff [REDACTED]  
[REDACTED].” (Ex. D, April 4, 2017 Dr. Shanon Smith Deposition Transcript (“Smith Dep. Tr.”) at 123:2-12.)

5. Plaintiff has a complex medical history that includes [REDACTED]

[REDACTED] (Ex. C, Selected Plaintiff Medical Records.)

6. Plaintiff testified that, shortly after she received her filter in 2009, she began [REDACTED].  
(Ex. E, February 20, 2017 Carol Kruse Deposition Transcript (“Kruse Dep. Tr.”) at 127:21 to 128:16.)

7. Plaintiff testified that in approximately late 2010, before she underwent an attempted removal procedure, [REDACTED]

[REDACTED] (Ex. E, Kruse Dep. Tr. at 129:16 to

1 130:3; 134:4-17.)

2 8. Plaintiff testified that in 2009 or 2010, she saw TV advertisements soliciting  
3 potential IVC filter plaintiffs. (Ex. E, Kruse Dep. Tr. at 45:6-23.)

4 9. Plaintiff testified that she saw these TV advertisements soliciting potential  
5 IVC filter plaintiffs before she underwent her Filter removal procedure in April 2011. Ex.  
6 E, Kruse Dep. Tr. at 48:23 to 49:7.)

7 10. Plaintiff testified that, within “a couple of weeks” of seeing the TV  
8 advertisements soliciting potential IVC filter plaintiffs, she called the phone number she  
9 saw on the advertisement regarding her potential IVC filter claim. (Ex. E, Kruse Dep. Tr.  
10 at 45:24 to 46:15.)

11 11. Although it was “years” before she formally hired an attorney regarding her  
12 potential IVC filter lawsuit, Plaintiff testified that she periodically received letters  
13 regarding her “case” from a lawyer named Russell Button. (Ex. E, Kruse Dep. Tr. at 46:24  
14 to 47:22.)

15 12. Plaintiff testified that she called her daughter shortly after seeing the TV  
16 advertisements regarding potential IVC filter lawsuits to discuss her IVC filter. (Ex. E,  
17 Kruse Dep. Tr. at 14:4-19.)

18 13. On March 14, 2011, Ms. Kruse visited her [REDACTED]  
19 [REDACTED] (Ex. C, Selected Plaintiff Medical Records.)

20 14. The medical record associated with this March 14, 2011, procedure notes  
21 Mr. Kruse [REDACTED]  
22 [REDACTED] (Ex. C, Selected Plaintiff Medical Records.)

23 15. As of March 14, 2011, Plaintiff was still having [REDACTED]  
24 [REDACTED]  
25 [REDACTED] (Ex. E, Kruse Dep. Tr. at 134:23 to 138:16.)

26 16. Plaintiff admits that at least as of April 7, 2011, she first attributed  
27 symptoms to her Bard G2 Filter. (Ex. A, PFS at § II.13(c).)

28 17. Dr. Smith testified that before he placed the Filter, he had the IFU that

1       accompanied the Filter available to him to read. (Ex. D, Smith Dep. Tr. at 152:25 to  
 2       153:6.)

3           18.      The G2 IFU applicable in July 2009 (when Plaintiff received her Filter)  
 4       contains specific warnings regarding the risks of filter tilt, migration, fracture, perforation,  
 5       and inability to retrieve. (Ex. B, G2 IFU.)

6           19.      Specifically, the IFU states as follows:

7               a.       Under the bolded heading “**Potential Complications**,” the G2 IFU  
 8       reads as follows:

- 9               • Movement or migration of the filter is a known complication of vena  
 10       cava filters.
- 11               • Filter fracture is a known complication of vena cava filters.
- 12               • Perforation or other acute or chronic damage of the IVC wall.

13               \* \* \*

14               **All of the above complications have been associated with serious  
 15       adverse events such as medical intervention and/or death. There have  
 16       been reports of complications including death, associated with the use  
 17       of vena cava filters in morbidly obese patients. The risk/benefit ratio of  
 18       any of these complications should be weighed against the inherent  
 19       risk/benefit ration for a patient who is at risk of pulmonary embolism  
 20       without intervention.**

21       (Ex. B, G2 IFU.)

22               b.       In the bolded “**Clinical Experience**” section, the IFU notes that in  
 23       the clinical trial regarding the G2 Filter, “filter tilt” was observed 15 times, and that  
 24       there were “3 technical failures for retrieval resulted from inability to engage the  
 25       filter apex with the Recovery Cone® Removal System due to filter tilt leading to  
 26       embedding of the filter apex into the vena caval wall.” (Ex. B, G2 IFU.)

27               c.       Under the bolded “**G2® Filter Removal**” heading, the G2 IFU states  
 28       in bolded language as follows:

1           **It is possible that complications such as those described in the**  
 2           **“Warnings”, “Precautions,” and “Potential Complications” sections of**  
 3           **this Instructions for Use may affect the recoverability of the device and**  
 4           **result in the clinician’s decision to have the device remain permanently**  
 5           **implanted.**

6           (Ex. B, G2 IFU.)

7           20. Dr. Smith testified that he was independently aware of the risks of filter tilt,  
 8 migration, perforation, and fracture, and that he would have discussed with Plaintiff the  
 9 potential complications associated with her receiving an IVC filter. (Ex. D, Smith Dep. Tr.  
 10 at 100:2-14; 153:7-17.)

11          21. Dr. Smith testified that more information is helpful. (Ex. D, Smith Dep. Tr.  
 12 at 181:16-20.)

13          22. Dr. Smith never testified that had he received some additional information  
 14 from Bard, he would have used a different device with Plaintiff.

15          23. Dr. Smith testified that “it’s possible” he would have changed his treatment  
 16 of Plaintiff had he received some additional information from Bard about the G2 Filter.  
 17 (Ex. D, Smith Dep. Tr. at 60:25 to 62:3.)

18          24. When asked whether the alleged facts and documents shown to Dr. Smith  
 19 by Plaintiff’s counsel would have changed his decision to use a G2 Filter with Plaintiff,  
 20 Dr. Smith testified that he “wouldn’t want to say how they would influence me without  
 21 knowing what they say in detail.” (Ex. D, Smith Dep. Tr. at 148:21 to 149:5.)

22          25. Dr. Smith testified that he relied on his training, experience, the experience  
 23 of his colleagues, and the applicable medical literature when he makes treatment decisions  
 24 regarding his patients, including Ms. Kruse. (Ex. D, Smith Dep. Tr. at 145:21 to 146:12.)

25          26. Dr. Smith did not testify that he relied on any statement by Bard, or any  
 26 omission of material fact, in deciding to use the Filter.

27          27. On April 7, 2011, Plaintiff underwent an unsuccessful percutaneous filter  
 28 removal procedure. (Ex. A, PFS at § II.11.)

1       28. Dr. Smith attempted [REDACTED]  
2 [REDACTED]  
3 [REDACTED] (Ex. D, Smith Dep. Tr. at 74:16-25.)

4       29. Plaintiff's vascular and interventional radiologist expert, Dr. Darren Hurst,  
5 testified that Plaintiff's Filter could "likely" be removed via a complex percutaneous  
6 procedure. (Ex. F, July 21, 2017 Dr. Darren Hurst Deposition Transcript at 159:1-11.)

7       30. On February 5, 2013, Plaintiff filed a Chapter 7 Bankruptcy Petition. (Ex.  
8 G, Carol Kruse Bankruptcy Case (Case No. 13-40196-TLS, U.S Bankruptcy Court,  
9 District of Nebraska (Lincoln Office)), Bankruptcy Petition ("Kruse Bankruptcy Petition");  
10 Ex. E, Kruse Dep. Tr. at 187:8-20.)

11       31. In her Petition, Plaintiff filled out a Schedule in which she verified all of her  
12 "personal property . . . of whatever kind." (Ex. G, Kruse Bankruptcy Petition, Schedule B  
13 - Personal Property.)

14       32. Under No. 21 ("Other contingent and unliquidated claims of every nature")  
15 of Schedule B of her Bankruptcy Petition, Plaintiff marked an "X" for "NONE." (Ex. G,  
16 Kruse Bankruptcy Petition, Schedule B - Personal Property, No. 21.)

17       33. Under No. 35 ("Other personal property of any kind not already listed") of  
18 Schedule B of her Bankruptcy Petition, Plaintiff marked an "X" for "NONE." (Ex. G,  
19 Kruse Bankruptcy Petition, Schedule B - Personal Property, No. 35.)

20       34. Plaintiff filled out "Schedule F - Creditors Holding Unsecured Nonpriority  
21 Claims," in which she identified \$36,067.44 in such claims. (Ex. G, Kruse Bankruptcy  
22 Petition, Schedule F -Creditors Holding Unsecured Nonpriority Claims.)

23       35. Plaintiff signed the Petition, declaring under penalty of perjury that the  
24 information provided in the Petition is true and correct. (Ex. G, Kruse Bankruptcy Petition  
25 at page 3 ("Signatures").)

26       36. On February 8, 2013, an Interim Trustee was appointed to Plaintiff's  
27 bankruptcy estate. (Ex. H, Carol Kruse Bankruptcy Case (Case No. 13-40196-TLS, U.S  
28 Bankruptcy Court, District of Nebraska (Lincoln Office)), Notice of Chapter 7

Bankruptcy Case, Meeting of Creditors, & Deadlines.)

37. On April 1, 2013, after making a “diligent inquiry into the financial affairs” of Plaintiff, the bankruptcy trustee declared that he did not “receive[] any property” for the estate, and that “there is no property available for distribution,” and he certified that Plaintiff’s estate has been fully administered. (Ex. I, Carol Kruse Bankruptcy Case (Case No. 13-40196-TLS, U.S Bankruptcy Court, District of Nebraska (Lincoln Office)) Docket Report (“Kruse Bankruptcy Docket Report”) at No. 7.)

38. On June 3, 2013, Plaintiff obtained a bankruptcy discharge order. (Ex. J, Carol Kruse Bankruptcy Case (Case No. 13-40196-TLS, U.S Bankruptcy Court, District of Nebraska (Lincoln Office)), Discharge Order; Ex. E, Kruse Dep. Tr. at 187:24 to 188:16.)

39. As of the date of this filing, Plaintiff has not filed a motion to reopen her bankruptcy estate. (Ex. I, Kruse Bankruptcy Docket Report.)

40. Plaintiff testified that she never spoke to anyone at Bard. (Ex. E, Kruse Dep. Tr. at 187:1-3.)

41. Plaintiff testified that she never received any written or verbal information about her filter before she received it. (Ex. A, PFS at § II.8.)

42. Plaintiff testified that she never researched IVC filters. (Ex. E, Kruse Dep. Tr. at 87:25 to 88:5.)

43. Plaintiff testified that she did not know that Bard was the manufacturer of her Filter until the day she underwent her unsuccessful retrieval procedure. (Ex. E, Kruse Dep. Tr. 87:8-24.)

RESPECTFULLY SUBMITTED this 28th day of August, 2017.

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9 **Attorneys for Defendants C. R. Bard, Inc. and**  
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## **CERTIFICATE OF SERVICE**

I hereby certify that on this 28th day of August 2017, the foregoing was electronically filed with the Clerk of Court using the CM/ECF system which will automatically send email notification of such filing to all attorneys of record.

s/Richard B. North, Jr.  
Richard B. North, Jr.